REMARKS

I. Status of the Application

Claims 1 -29 are presently pending in the application. Claims 15-17 and 25-28 have been withdrawn pursuant to a restriction requirement. Claims 13-14 and 20-21 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claims 8, 11, 18-24 and 29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 2, 7-9, 12-14 and 18-21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by www.stlukeseye.com/Conditions/ForeignBody.asp. Claims 1-3, 6-14 and 18-21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Young et al. (U.S. Patent No. 6,656,222) ("Young"). Claims 1, 2, 6-10, 12-14, 18-23 and 29 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lynch et al. (U.S. Patent No. 6,783,544) ("Lynch"). Claims 22 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pynson et al. (U.S. Patent No. 5,879,319) ("Pynson"). Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Young. Claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Lynch. Claim 24 also stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Pynson.

Claims 8, 11, 13, 14, 19, 20, 21, 22, 23 and 29 have been amended to correct formal matters. Claim 11 has been amended to delete the box or pouch limitation, which has been copied to new dependent claim 30. Claim 18 has been amended to delete the hyaluronic acid limitation, which has been copied to new dependent claim 31. Claim 22 has been amended to delete the self-sealing limitation, which has been copied to new dependent claim 32.

Applicant submits that the amended claims contain no new matter. Reconsideration of the application in view of the following remarks, and allowance of claims 1-14, 18-24 and 29-31 is respectfully requested.

II. Claims 13-14 and 20-21 Are Directed to Statutory Subject Matter

On page 2, paragraph 3 of the instant Office Action, claims 13-14 and 20-21 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicant respectfully traverses this rejection based on the amended claims.

As advised by the Examiner, claims 13 and 14 have been amended to recite an eye implant according to claim 1, adapted to be positioned on/in an eye. Claim 20 has been amended to recite a cosmetic eye implant adapted to be positioned in, on or between the conjunctiva, sclera, cornea and/or iris of an eye of a vertebrate Claim 21 has also been amended to recite an eye implant. Support for this amendment can be found on page 1, lines 22-24 of the specification. Claims 13-14 and 20-21 no longer recite an eye, so are not directed to non-statutory subject matter. Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 101 and allowance of claims 13-14 and 20-21.

III. Claims 8, 11, 18-24 and 29 Are Definite

On page 3, paragraph 1 of the instant Office Action, claims 8, 11, 18-24 and 29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as

the invention. Applicant respectfully traverses this rejection based on the amended claims.

Claim 8 has been amended into proper Markush format. Claim 11 has been amended to delete "like" terminology. Claim 18 has been amended to delete "for example" clauses. The hyaluronic acid limitation has been moved to new dependent claim 30. Claim 19 has been amended into independent format, and also to remove "use" terminology. Claims 20 and 21 have been amended to claim a "cosmetic eye implant," so as to have consistent scope with preceding claims. Claim 22 has been amended to cite "an element" as suggested by the Examiner. Claim 22 has been further amended to delete the self-sealing closing method, so that dependent claim 23 is consistent with it. Claim 23 has also been amended to complete the preamble and delete "or the like" terminology. Claims 19 and 29 have been amended into independent format.

Applicant submits that due to the above amendments, the claims do particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, second paragraph rejection and allowance of claims 8, 11, 18-24 and 29.

IV. Claims 1, 2, 7-9, 12-14 and 18-21 Are Not Anticipated by Site Publication

On page 4, paragraph 3 of the instant Office Action, claims 1, 2, 7-9, 12-14 and 18-21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by site publication www.stlukeseye.com/Conditions/ForeignBody.asp, previously published on 11/23/01 and 8/8/02. The Examiner contends that the site publication teaches each and every element of the claims. Applicant respectfully traverses this rejection.

Applicant's invention is directed to an eye implant comprising a flat element made of biocompatible material, said element being made at least partly opaque or light reflecting, such that in use the eye implant shall be visible, once implanted in an eye. Applicant's invention is also directed to a cosmetic eye implant adapted to be positioned in, on or between the conjunctiva, sclera, cornea and/or iris of an eye of a vertebrate. A precondition for such an implant is that it does not irritate the eye or in any other way impede the normal function of the eye (see specification page 2, lines 14-16 and 25-30).

The site publication does not teach a useful invention that meets the utility requirements of 35 U.S.C. §§ 101 and 112, first paragraph. The site publication is entitled "Foreign Body," and describes the unintentional presence of said foreign body in the eye as causing irritation to intense, excruciating pain (page 1 under "Signs and Symptoms"). This shows that the disclosed materials (grain of sand and nail chip) are **not** adapted to be positioned in an eye, and serve no useful purpose. Furthermore, the site publication states "[i]f a foreign object becomes embedded within the cornea, conjuctiva, or sclera, a medical professional **must remove it**." (page 2 under "Treatment") (Emphasis added.) Thus, the site publication does not teach an operable eye implant, so does not provide an enabling disclosure of the claimed invention. "The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). The site publication does not disclose surgical methods for intentionally implanting said foreign body into the eye, and determining the correct

surgical technique would require undue experimentation. Thus, the site publication does not teach a grain of sand or a nail chip as **visible/cosmetic eye implants** as in independent claims 1 and 19, nor are they taught as being **adapted to be positioned** in, on or between the conjunctiva, sclera, cornea and/or iris of an eye as in independent claim 20.

In addition, the Examiner is of the opinion that the site publication teaches sand or a nail chip as a flat element. Applicant respectfully disagrees. The specification defines flat as "having a thickness in a first direction which is considerably less than the measurements perpendicular to said first direction" (page 2, lines 2-4). The site publication discloses a grain of sand (first page, first paragraph). One skilled in the art would not construe "grain" to teach any particular shape. The disclosed nail chip (page 1, illustration) has an "L" shape and does not show thickness. Therefore, the site publication does not teach a flat element as claimed and defined by Applicant.

The Examiner further states that any sharp edge of sand or nail chip as disclosed in the site publication may be considered a means of attachment as in dependent claim 12. However, such sharp edge would form a cutting edge leading to further insertion of said foreign body into the eye instead of "attaching" or, as will commonly be the case, over time the sharp cutting edge of the foreign body will allow it to be forced out by the eye tissue and movement of the eye. Therefore, said sharp edge cannot be considered attachment means within the meaning of the present application.

The site publication does not teach each and every limitation of independent claims 1 with dependent claims 2, 7-9, 12-14 and 18, independent claim 19 and

independent claim 20 with dependent claim 21. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of claims 1, 2, 7-9, 12-14 and 18-21.

V. Claims 1-3, 6-14 and 18-21 Are Novel over Young

On page 5, paragraph 2 of the instant Office Action, claims 1-3, 6-14 and 18-21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Young et al. (US 6,656,222) ("Young"). The Examiner contends that Young teaches each and every element of the claims. Applicant respectfully traverses this rejection.

The Examiner is of the opinion that Young discloses an implantable intraocular lens with non-limiting "intended use" language. Applicant respectfully disagrees. Young discloses an intraocular lens for use in replacing the natural lens of a human eye (column 1, lines 11-13). The intraocular lens of Young is designed to be inserted into the capsular bag of the eye (column 1, 56-61 and column 4, line 36), which is centralized over the axis of vision behind the pupil. These are not statements of intended use, but limitations on the structure of the implant. An implant **designed** to be placed in the capsular bag of the eye is structured so as to fit specifically into that area of the eye. In fact, the implant according to Young is far too thick and wide to be placed in, on or between the conjunctiva, sclera, cornea and/or iris. Even, if one were to try to do so, it would not be possible without irritating and impairing the normal function of the eye. For example, Young teaches a biconvex optical portion of the disclosed intraocular lens (column 4, lines 16-17), which mimics the shape of a natural lens, but does not teach the one concave and one convex surface of claim 10, which mimics the curvature of the surface of the eye. Placement of Young's intraocular lens as in claim 20 would require

deformation of the lens by bending it to follow the curvature of the surface of the eye. This would either be impossible due to the material composition of Young's intraocular lens, or lead to unallowable strain on the layers of the eye. Also, the eyelid would have difficulty closing over the deformed shape of the eye.

The capsular bag is located posterior to the iris, which allows light into the eye through the pupil. Once implanted into the capsular bag of the eye, only the transparent optic portion of Young's intraocular lens can be viewed through the pupil, although it is not visible due to being transparent. The opaque cell barrier portion of Young's implanted lens is not visible to an individual looking into the eye because it is obscured by the iris. Because Young's disclosure is a limitation of structure and not an intended use, Young's intraocular lens is not capable of being implanted elsewhere in the eye so that the opaque cell barrier portion is visible. Young's lens is not designed to serve a cosmetic purpose, so is not designed to be visible once implanted in the eye as required by independent claims 1 or 19. In addition, Young's intraocular lens is not substantially opaque as required by dependent claim 2.

Young does not disclose an implant adapted to be positioned in, on or between the conjunctiva, sclera, cornea and/or iris of an eye, as required by independent claim 20. "Adapted to be" is also a statement of structural limitation, not intended use. In contrast, Young teaches an implant adapted to be positioned in the capsular bag (column 1, lines 58-60), which requires a structurally different implant than one adapted for the conjunctiva, sclera, cornea and/or iris.

The Examiner asserts that Young's intraocular lens comprises multiple particles (15, 17, 13, 21). Particle is defined by Webster's Ninth New Collegiate Dictionary as "3

a: a minute quantity or fragment b: a relatively small or the smallest possible discrete portion or amount of something." Fixation members 15 and 17, optic 13 and cell barrier portion 21 of Young's intraocular lens are not minute quantities or smallest possible amounts. Neither are they fragments ("a part broken off, detached or incomplete" according to Webster's) or discrete portions, because they are connected parts of a whole device. Therefore, Young does not teach multiple particles as required by dependent claim 18.

The Examiner asserts that Young's intraocular lens inherently comes in a sterilized container as all surgical material is. However, since Young is entirely silent on a container or sterilization, Young cannot be said to teach each and every limitation of claim 11. For example, Young's lens may be sterilized outside of any container immediately before use. So Young does not inherently teach an eye implant enclosed in a closed container, said eye implant being sterilized or sterilizable within said container.

Therefore, Young does not teach each and every limitation of independent claim 1 with dependent claims 2-3, 6-14 and 18, independent claim 19 and independent claim 20 with dependent claim 21. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of claims 1-3, 6-14 and 18-21.

VI. Claims 1, 2, 6-10, 12-14, 18-23 and 29 Are Novel over Lynch

On page 5, paragraph 3 of the instant Office Action, claims 1, 2, 6-10, 12-14, 18-23 and 29 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lynch et al. (US 6,783,544) ("Lynch"). The Examiner contends that Lynch teaches each and every element of the claims. Applicant respectfully traverses this rejection.

The Examiner is of the opinion that the stent device of Lynch is visible outside the eye upon implantation in the eye. Applicant respectfully disagrees. As with Young above, Lynch does not describe the invention with statements of intended use, but with limitations on the structure of the implant. Thus, when Lynch discloses a stent device comprising a body portion shaped to be wholly received within Schlemm's canal (column 4, line 64 to column 5, line 3) or adapted to be wholly retained within a portion of Schlemm's canal (claim 1), Lynch discloses structural limitations that make the invention suitable for implantation into Schlemm's canal and not other parts of the eye. Schlemm's canal is located within the sclera, which is the white part of the eye and not transparent. Therefore, the stent device of Lynch implanted into Schlemm's canal would not be visible. In addition, Lynch's stent device is not designed to serve a cosmetic purpose, so is not designed to be visible once implanted in the eye. Thus, Lynch does not teach each and every element of independent claims 1 and 19.

Schlemm's canal is not a part of the sclera, so Lynch's stent device is not adapted to be positioned in, on or between the conjunctiva, sclera, cornea and/or iris, as required by independent claim 20. Lynch does not teach the step of "inserting said element in the conjunctiva or between the conjunctiva and the sclera through said opening" as required by independent claim 22. Lynch teaches inserting the stent into Schlemm's canal, which is not in the conjunctiva or between the conjunctiva and the sclera. Lynch does not teach all the components of the set of claim 29. Specifically, Lynch does not teach an eye implant visible once implanted in an eye, a scalpel or forceps.

Therefore, Lynch does not teach each and every element of independent claim 1 with dependent claims 2, 6-10, 12-14 and 18, independent claim 19, independent claim

20 with dependent claim 21, independent claim 22 with dependent claim 23, and independent claim 29. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of claims 1, 2, 6-10, 12-14, 18-23 and 29.

VII. Claims 22 and 23 Are Novel over Pynson

On page 6, paragraph 2 of the instant Office Action, claims 22 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pynson et al. (US 5,879,319) ("Pynson"). The Examiner contends that Pynson teaches each and every element of the claims. Applicant respectfully traverses this rejection.

The Examiner is of the opinion that Pynson teaches a method for implanting an element in the eye comprising an at least partially opaque element (PMMA implant). Applicant respectfully disagrees. Pynson does not teach an implant made of polymethylmethacrylate (PMMA). Pynson teaches an eye implant made of methylmethacrylate/vinylpyrrolidone copolymer (column 4, lines 17-20). This copolymer is shown to be transparent in a photograph on website publication http://www.iopinc.com/surgeons_and_medical_professionals/osmed/. The website also describes this copolymer as similar to what is used to manufacture soft contact lenses, which are necessarily transparent (first paragraph under "Hydrogel Tissue Expanders"). Indeed, Pynson's device is not designed to serve a cosmetic purpose, so is not designed to be visible once implanted in the eye Hence, the disclosure of a transparent copolymer as the material of choice for Pynson's eye fluid drainage device. Therefore, Pynson does not teach an at least partially opaque element as required by independent claim 22.

Furthermore, Pynson discloses a sclerotomy implant which has a function similar to that of the stent according to Lynch. Pynson's sclerotomy implant is inserted in the sclera with a first part against or close to the sinus venosus and the opposite second end against the conjunctiva. Thus, Pynson does not disclose insertion of an implant in the conjunctiva or between the conjunctiva and the sclera, as required by claim 22. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of independent claim 22 with dependent claim 23.

VIII. Claims 4 and 5 Are Not Obvious over Young

On page 6, paragraph 4 of the instant Office Action, claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Young et al. (US 6,656,222) ("Young"). The Examiner contends that the claims are obvious in view of Young. Applicant respectfully traverses this rejection.

> A *prima facie* case of obviousness requires three showings:
>
> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.
>
> Manual of Patent Examining Procedure, 8th ed., § 2142.

The Examiner is of the opinion that modifying the intraocular lens of Young to the size dimensions of claims 4 and 5 is an obvious design choice to one of ordinary skill in the art. Applicant has already distinguished the claimed invention from that of Young

in section V above, so Young does not teach each and every limitation of independent claim 1, from which claims 4 and 5 depend. The Examiner admits that Young does not teach the size limitations of claims 4 and 5. Also, the claimed invention is not obvious over Young because Young in no way provides motivation to implant the disclosed intraocular lens anywhere in the eye other than the capsular bag, so Young does not provide motivation for a visible eye implant. Since Young's intraocular lens is designed for a different purpose (focusing light on the retina) than that of the claimed invention (cosmetic appearance), one of ordinary skill in the art would not be motivated by Young to modify the size of the intraocular lens to that disclosed by claims 4 and 5 with any expectation of success to achieve a visible (cosmetic) eye implant.

In addition, Young does not provide motivation to alter the dimensions of the disclosed intraocular lens to those of claims 4 and 5, because miniaturizing it in such a manner would render the lens inoperable for its intended purpose of fitting in the capsular bag of the eye and focusing light on the retina. "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

A *prima facie* case of obviousness cannot be made because Young does not provide motivation to modify the reference teachings with a reasonable expectation of success, nor does Young teach or suggest all the claim limitations. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of claims 4 and 5.

IX. Claim 24 Is Not Obvious over Lynch

On page 7, paragraph 1 of the instant Office Action, claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Lynch et al. (US 6,783,544) ("Lynch"). The Examiner contends that the claim is obvious in view of Lynch. Applicant respectfully traverses this rejection.

Applicant has already distinguished the claimed invention from that of Lynch in section VI above, so Lynch does not teach each and every limitation of claim 22 from which claim 24 depends. The Examiner admits that Lynch does not teach the distance from the implantation site to the limbus required by claim 24. The stent device of Lynch is designed to be inserted into Schlemm's canal, which is not in a conjunctive area of the eye, as required by claim 24. Thus, Lynch does not teach or suggest each and every limitation of claim 24.

Also, because Lynch teaches implantation of the stent device into Schlemm's canal in order to drain fluid, implanting the stent elsewhere in a conjunctive area spaced 2 to 5 mm apart from the limbus would render Lynch's invention inoperable. "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

A *prima facie* case of obviousness cannot be made because Lynch does not provide motivation to modify the reference teachings with a reasonable expectation of success, nor does Lynch teach or suggest all the claim limitations. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of claim 24.

X. Claim 24 Is Not Obvious over Pynson

On page 7, paragraph 2 of the instant Office Action, claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Pynson et al. (US 5,879,319) ("Pynson"). The Examiner contends that the claims are obvious in view of Pynson. Applicant respectfully traverses this rejection.

Applicant has already distinguished the claimed invention from that of Pynson in section VII above, so Pynson does not teach each and every limitation of claim 22, from which claim 24 depends. Specifically, the implant of Pynson is transparent, so Pynson does not teach an at least partly opaque implant. The Examiner admits that Pynson does not teach the distance from the implantation site to the limbus required by claim 24. Thus Pynson does not teach or suggest each and every limitation of claim 24.

Pynson does teach making an incision in the trabeculum and then placing the trabecular end of the implant beside the trabecular incision (column 5, lines 30- 33, figures 5-8). Since the trabeculum (limbus) is the place where the cornea connects to the sclera, Pynson teaches away from implanting the device 2-5 mm apart from the limbus. To do so would make the invention of Pynson inoperable for draining fluid through the trabecular incision. "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

A *prima facie* case of obviousness cannot be made because Pynson does not provide motivation to modify the reference teachings with a reasonable expectation of

success, nor does Pynson teach or suggest all the claim limitations. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of claim 24.

IV. Conclusion

In view of the foregoing amendments and remarks, pending claims 1-14, 18-24 and 29-32 are believed to be allowable, and an indication to that effect from the Examiner is respectfully requested at this time. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-referenced application, the Examiner is urged to call the undersigned at the number below.

Please apply any required charges or credits to our Deposit Account No. 19-0733.

Respectfully submitted,

Dated: April 7, 2006

By _____

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